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## INTELLECTUAL PROPERTY LAW

IFW

June 16, 2004



Anita Nador B.A. (Molec. Biophys./Biochem), LL.B. 416 957 1684 anador@bereskinparr.com

Your Reference: 10/782,871 Our Reference: 11157-74

Commissioner for Patents and Trademarks Washington, D.C. 20231 U.S.A.

Dear Sir:

Re: FILING OF AN INFORMATION DISCLOSURE STATEMENT

United States Patent Application No. 10/782,871

(Continuation-In-Part of U.S. Application No. 09/645,594)

**Entitled:** 

Use of Charged Dextran as a Mucoactive Agent and Methods

and Pharmaceutical Compositions Relating Thereto

Inventors: Malcolm King

Filing Date: February 23, 2004

Grp Art Unit: 1617

Examiner: Lauren Q. Wells

In accordance with 37 CFR 1.97 and 1.98, and in recognition of the duty of disclosure set forth in 37 CFR 1.56, Applicant hereby submits an Information Disclosure Statement on Form PTO-SB08A containing a listing of patents and other publications of which Applicant is aware. Applicant is also submitting the references listed on the Information Disclosure Statement.

All of the patents and publications submitted herewith are in the English language.

Accordingly a concise explanation of the relevance of the documents is not required.

The Examiner is requested to indicate consideration of these documents by initialling the appropriate column.

Please send all correspondence to the Toronto office:

Applicants reserve the right to contest the applicability of any of these documents as prior art against the subject application. If the Examiner has any questions concerning this Information Disclosure Statement, he/she is requested to contact the undersigned. Entry of the enclosed Information Disclosure Statement is believed to be in order and is respectfully requested.

This Information Disclosure Statement is being filed before the issuance of a first official action, and therefore no fees are required. However, please charge our deposit account No. 02-2095 if such a fee is required.

Respectfully submitted,

#### **MALCOLM KING**

Anita Nador

Registration No. 47, 366

Bereskin & Parr Box 401, 40 King Street West Toronto, Ontario, Canada M5H 3Y2

Tel. (416) 364-7311

Approved for use through 10/31/2002, OMB 0651-0031

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Sustitute for form 1449A/PTO ☆MFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete if Known Application Number 10/782,871 February 23, 2004 Filing Date First Named Inventor Malcolm King Group Art Unit 1617 **Examiner Name** Attorney Docket Number 11157-74

(use as many sheets as necessary) Sheet of 6

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**U.S. PATENT DOCUMENTS** Name of Patentee or Applicant of **Document Number** Publication Date Pages, Columns, Lines, Where Relevant Passages or Relevant Cite No.1 Examiner Cited Document MM-DD-YYYY Initials Number - Kind Code<sup>2</sup> (if known) Figures Appear Speert et al. US-5,514,665 2 US- 5,980,865 Ahmed Yacoby-Zeevi 3 US-6,153,187 4 US- 5,968,822 Pecker et al. US-US-US-US-US-US-US-US-US-US-US-US-US-

	FOREIGN PATENT DOCUMENTS						
-		Foreign Patent Document	D. Allertine	Name of Patentee or	Pages, Columns, Lines, Where Relevant		
Examiner Initials*	Cite No.1	Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Applicant of Cited Document	Passages or Relevant Figures Appear	τ <sup>6</sup>	
7	1	WO 91/15216 PCT	10-17-1991	Kennedy			
	, 2	WO 95/17898	07-06-1995	Novadex Pharm Ltd.			
١	3	WO 93/08810 PCT	05-13-1993	Carrington Lab INC			
7	4	EP 0177783	04-16-1986	Kanto Ishi Pharma et al.			

Examiner Signature	Date Considered	

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( 5	Substitute	for form 1449	PA/PTO		Complete if Known		
			<b>^  </b>	01.001155	Application Number	10/782,871	
_				CLOSURE	Filing Date	February 23, 2004	
,	STATEMENT BY APPLICANT				First Named Inventor	Malcolm King	
					Group Art Unit	1617	
	(use as many sheets as necessary)				Examiner Name		
Ţ	Sheet	2	of	6	Attorney Docket Number	11157-74	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	1	KING, M., AND B.K. RUBIN. 1996. Mucus physiology and pathophysiology: Therapeutic aspects. Chapter 13 of: Derenne, J.P., W.A. Whitelaw, and T. Similowski, eds. Acute Respiratory Failure in COPD (Lung Biology in Health and Disease Series) Marcel Dekker, New York, 391-411.	
	2	RUBIN, B.K., R.P. TOMKIEWICZ, AND M. KING. 1997. Mucoactive agents: Old and new. Chapter 7 of: Wilmott, R.W., ed. The Pediatric Lung. Birkhduser, Basel, 155-179.	
	3	SHEFFNER, A.L. 1963. The reduction in vitro in viscosity of mucoprotein solutions by a new mucolytic agent, Nacetylcysteine. Ann. N. Y. Acad. Sci. 106:298-310.	
	4	DASGUPTA, B., AND M. KING. 1996. Reduction in viscoelasticity of cystic fibrosis sputum in vitro with combined treatment by Nacystelyn and rhDNase. Pediatr. Pulmonol. 22:161-166.	
	5	APP, E.M., R. KIESELMANN, D. REINHARDT, H. LINDEMANN, B. DASGUPTA, M. KING, AND P. BRAND. 1998. Sputum rheology changes in cystic fibrosis lung disease following two different types of physiotherapy: Flutter vs. autogenic drainage. Chest 114:171-177.	
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	7	WILLS, P.J., R.L. HALL, W.M. CHAN, AND P.J. COLE. 1997. Sodium chloride increases the ciliary transportability of cystic fibrosis and bronchiectasis sputum on the mucus-depleted bovine trachea. J. Clin. Invest. 99:9-13.	
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	10	VASCONCELLOS, C.A., P.G. ALLEN, M. WOHL, J.M. DRAZEN, AND P.A. JANMEY. 1994. Reduction in sputum viscosity of cystic fibrosis sputum in vitro by gelsolin. Science 263:969-971.	
	11	DAVISKAS, E., S.D. ANDERSON, J.D. BRANNAN, H.K. CHAN, S. EBERL, AND G. BAUTOVICH. 1997. Inhalation of dry-powder mannitol increases mucociliary clearance. Eur. Respir. J. 10:2449-2454.	

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Substitute	for form 1449A/PT	0			Complete if Known
			01.001155	Application Number	10/782,871
			CLOSURE	Filing Date	February 23, 2004
STAT	rement b	BY A	PPLICANT	First Named Inventor	Malcolm King
				Group Art Unit	1617
	(use as many sh	neets as	necessary)	Examiner Name	
Sheet	3	of	6	Attorney Docket Number	11157-74

	,	OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	12	SHIBUYA, Y., P.J. WILLS, S. KITAMURA, AND P.J. COLE. 1997. The effects of lactose on mucociliary transportability and rheology of cystic fibrosis and bronchiectasis sputum. Eur. Respir. J. 10:321s.	
	13	FUCHS, H.J., D.S. BOROWITZ, D.H. CHRISTIANSEN, E.M. MORRIS, M.L. NASH, B.W. RAMSEY, B.J. ROSENSTEIN, A.L. SMITH, AND M.E. WOHL. 1994. Effect of aerosolized recombinant human DNase on exacerbations of respiratory symptoms and on pulmonary function in cystic fibrosis. N. Engl. J. Med. 33:637-648.	
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	16	FENG, W., S. NAKAMURA, E. SUDO, M.M. LEE, A. SHAO, AND M. KING. 1999. Effects of dextran on tracheal mucociliary velocity in dogs in vivo. Pulm. Pharmacol. Ther. 12:35-41.	
	17	LEE, M.M., AND M. KING. 1998. Effect of low molecular weight heparin on the elasticity of dog mucus. Clin. Invest Med. 21:S 102.	
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	19	APP, E.M., J.G. ZAYAS, AND M. KING. 1993, Rheology of mucus and epithelial potential difference: Small airways vs. trachea. Eur. Respir, J. 6: 67-75.	
	20	KING, M., S. KELLY, AND M. COSIO. 1985. Alteration of airway reactivity by mucus. Respiration Physiol. 62:47-59.	
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	22	KING, M. 1987. The role of mucus viscoelasticity in cough clearance. Biorheology 24: 589-597.	

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			D.O.		Application Number	10/782,871	
				CLOSURE	Filing Date	February 23, 2004	
	STAT	EMENT B	Y A	PPLICANT	First Named Inventor	Malcolm King	
					Group Art Unit	1617	
	(	use as many she	ets as	necessary)	Examiner Name		
abla	Sheet	4	of	6	Attorney Docket Number	11157-74	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
•	23	RUBIN, B.K., O. RAMIREZ, J.G. ZAYAS, B. FINEGAN, AND M. KING. 1990. Collection and analysis of respiratory mucus from individuals without lung disease. Am. Rev. Respir. Dis. 141:1040-1043.	
	24	DAVISKAS, E., S.D. ANDERSON, I. GONDA, S. EBERL, S. MEIKLE, J.P. SEALE, AND G. BAUTOVICH. 1996. Inhalation of hypertonic saline aerosol enhances mucociliary clearance in asthmatic and healthy subjects. Eur. Respir. J. 9:725-732.	
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	26	TOMKIEWICZ, R.P., W.A. BOYD, W. FENG, E.M. APP, B.K. RUBIN, AND M. KING. 1997. Tracheal clearance and mucus rheology in healthy dogs after aerosolization of 3% and 7% hypertonic saline. Am. J. Respir. Crit. Care Med. 155:A780.	
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	30	SUDO, E., M.M. LEE, W.A. BOYD, AND M. KING. 1998. Effect of methacholine and uridine-5' triphosphate on tracheal mucus rheology in mice. Pediatr. Pulmonol. S 17:229.	
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Examiner	Date	
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	Application Number	10/782,871	
INFORMATION DISCLOSURE	Filing Date	February 23, 2004	
STATEMENT BY APPLICANT	First Named Inventor	Malcolm King	
	Group Art Unit	1617	
(use as many sheets as necessary)	Examiner Name		
Sheet 5 of 6	Attorney Docket Number	11157-74	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	34	LORENTSEN, K.J., C.W. HENDRIX, J.M. COLLINS, D.M. KORNHAUSER, B.G. PETTY, R.W. KLECKER, C. FLEXNER, R.H. ECKEL, AND P.S. LIETMAN. 1989. Dextran sulfate is poorly absorbed after oral administration. Ann. Int. Med. 111: 561-566.	
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	37	MOTOJIMA S et al: "Effects of Anionic Polyelectrolyte Substance on Damages to Respiratory Epithelium Induced by Eosinophil Peroxidase", Dokkyo Journal of Medical Sciences, MIBU, JP, vol. 21, no. 2, 1994, pp. 123-134	
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	39	COYLE A. J. et al: "Role of Cationic Proteins in the Airway Hyperresponsiveness due to Airway Inflammation", American Journal of Respiratory and Critical Care Medicine, American Lung Association, New York, NY, US, vol. 150, no. 5, part 2, Nov. 1994, pp. S63-71.	
	40	BARGHOUTHI SAMEER et al.: "Inhibition by Dextran of Pseudomonas Aeruginosa Adherence to Epithelial Cells", American Journal of Respiratory and Critical Care Medicine", vol. 154, no. 6, part. 1, 1996, pp. 1788-1793.	
. <u>-</u>	41	COYLE ANTHONY J. et al.: "Cationic Proteins Induce Airway Hyperresponsiveness Dependent on Charge Interactions", American Review of Respiratory Disease, vol. 147, no. 4, 1993, pp. 896-900.	
	42	BARROWCLIFFE, MICHAEL P. et al.: "Pulmonary Clearance of Radiotracers After Positive End-Expiratory Pressure or Acute Lung Injury", J. Appl. Physiol. (1989), 66(1), 288-94.	
	43	BARROWCLIFFE M. P. et al.: "Clearance of Charged and Uncharged Dextrans from Normal and Injured Lungs", Journal of Aplied Physiology, vol. 68, no. 1, 1990. pp. 341-347.	
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Examiner	Date	
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		Application Number	10/782,871	
	ON DISCLOSURE	Filing Date	February 23, 2004	
STATEMEN	STATEMENT BY APPLICANT		Malcolm King	
		Group Art Unit	1617	
(use as ma	ny sheets as necessary)	Examiner Name		
Shoot 6	of 6	Attorney Docket Number	11157-74	

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	45	PAUL M. QUINTON, Physiological basis of cystic fibrosis: a historical perspective. Physiol Rev. 1999 Jan;79(1 Suppl):S3-S22.			
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